# Progress

- Oversight
  - Steering committee
    - CBER, CDER, CVM, CDRH*, CFSAN*, ORA, and the Office of the Commissioner
  - Seventeen working groups
- Six-month progress report issued 2/20/03
  - Nine milestones completed
- One-year progress report issued 9/3/03
  - Additional milestones completed

# Accomplishments To Date

- 21 CFR Part 11 – Electronic Records Requirements (Final Guidance) (8/28/03)
  - Withdraws earlier guidance
  - Clarifies scope and application of regulation
- Implementation of a Technical Dispute Resolution Process for CGMP Disputes (Draft Guidance) (8/25/03)
  - Domestic pilot study to begin 1/1/04

# Accomplishments To Date
continued

- Aseptic Processing Guidance (Draft) (8/22/03)
- Comparability Protocols (Draft Guidance) (2/13/03)
  - Applies to non-protein pharmaceuticals and veterinary drugs
- Process Analytical Technology (Draft Guidance) (8/25/03)

# Accomplishments To Date
continued

- Center review of all proposed drug CGMP Warning Letters started March 1, 2003
  - CBER had previously implemented review of all biological drug and device Warning Letters
- Language added to Form FDA 483
  - Clarifies that 483 items are inspectional observations and do not represent final FDA compliance determination
  - Notes that firm may discuss disagreement regarding an observation or a plan for corrective action with FDA representatives

# Accomplishments To Date
continued

- Scientific workshop held April 22-24, 2003, in Washington, DC
  - Topics included risk-based CGMP, integrated systems approach to CMC review and CGMP inspections, post-approval manufacturing changes, and manufacturing science
- Developing risk-based approach for choosing sites for inspections (CDER)
  - CBER already meets statutory obligations for inspecting all licensed facilities

# Accomplishments To Date
continued

- Review of Team Biologics operations
- Collaborations – material transfer agreements with Universities
  - To identify factors that predict manufacturing performance
  - To better target identified risks to pharmaceutical quality

# Accomplishments To Date
continued

- Pharmaceutical Inspectorate program established by ORA and CDER on 8/22/03
  - Highly trained individuals
  - Increased use of product specialists
  - Similar to existing Team Biologics and CBER biologics inspection practice (e.g., product specialists on inspections)
- Quality Systems Seminars
  - Internal FDA training

# Continuing International Collaboration

- Collaboration with other regulatory authorities, via ICH and other opportunities
- July 2003 ICH meeting
  - Agreement on development of international plan for harmonized pharmaceutical quality system applicable across life cycle of product
  - Emphasis on integrated approach to risk management and science

# Continuing International Collaboration
continued

- Two Expert Working Groups established
  - Pharmaceutical development
  - Define how risk management will be integrated into decisions regarding quality
- Development of consensus draft documents
  - Release planned for end of 2004

# Quality Management Systems

- Design of integrated Agency-wide, risk-based quality management system
- Three working groups established
  - Framework
  - Guidance
  - Harmonization

# Quality Systems Framework

- Development of framework that enhances and integrates Agency's existing quality systems
- Implemented in Centers and field to ensure consistency of reviews and inspections
- Common vocabulary and component description
- Draft white paper for internal FDA review by 10/31/03
- Public comment by 12/1/03

# Quality System Guidance Development

- Development of new educational guidance documents to encourage use of quality system principles
- First guidance expected to be released August 2004
- Report on Effective Quality System Practices contract in March 2004

# CGMP Harmonization Analysis

- Analyzing internal and external GMP requirements
- Review of regulations
  - 21 CFR 210 and 211
  - European Union CGMPs
  - PIC/S
  - Agency-wide CGMP regulations
- Differences noted will contribute to assessment of whether or not to revise 21 CFR 210 and 211
- Interim report by November 2003 and final report May 2004

# CBER's Existing CGMP Innovations Support FDA's Initiative

- Core Team of Investigators with specialized training in biologic drugs and devices
- Product specialists on-site or available during inspections
- All Warning Letters for biological drugs and devices reviewed by CBER
- Risk-based work planning
  - Products covered biennially
  - Most considered high-risk

# Further Information

- CGMP Initiative – Initial Announcement

  http://www.fda.gov/bbs/topics/NEWS/2002/NEW00829.html

- Six-Month Progress Report

  http://www.fda.gov/bbs/topics/NEWS/2003/NEW00872.html

- One-Year Progress Report
- http://www.fda.gov/bbs/topics/NEWS/2003/NEW00936.html

# Counter-Terrorism

- CBER plays critical and primary role in national counter-terrorism efforts
- Regulatory reviews and guidance
- Coordination with Government partners
- Leveraging with industry
- Implementation of CBER/FDA/DHHS policy

# Counter-Terrorism
continued

- Focus on expeditious development and licensing of products to diagnose, treat, or prevent outbreaks from exposure to biological agents
- Laboratory testing, methods/standards development, and lot release

# Counter-Terrorism
continued

- Work with manufacturers and others on product protocols, INDs, and licensing of critical products to meet national and international emergency needs
- Focus on manufacturing and product development areas
- Import/export
- Assure adequate reviewer and research base

# Counter-Terrorism
continued

- Collaborate with other government agencies (e.g., CDC, DOD, State Department) to facilitate product development and availability
- Surveillance of BT-related internet claims
- Increased surveillance of imported drugs/vaccines
- Further legislative proposals under consideration in Congress

# Counter-Terrorism
# FDA Internet Resources

http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html

http://www.fda.gov/oc/mcclellan/counterterrorism.html

http://www.fda.gov/cber/cntrbio/cntrbio.htm

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# Thank You